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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------------|------------------|
| 10/031,313   | 06/03/2002  | Michael Hallek       | 50125/044001                  | 5985             |
| 21559  | 7590        | 11/08/2004           |                               |                  |
| CLARK & ELBING LLP<br>101 FEDERAL STREET<br>BOSTON, MA 02110 |             |                      |                               |                  |
|  |             |                      | EXAMINER<br>CHEN, STACY BROWN |                  |
|  |             |                      | ART UNIT<br>1648              | PAPER NUMBER     |

DATE MAILED: 11/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/031,313

Applicant(s)

HALLEK ET AL.

Examiner

Stacy B Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 33-73 is/are pending in the application.
- 4a) Of the above claim(s) 33-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 72 and 73 is/are rejected.
- 7) ☒ Claim(s) 72 and 73 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/11/2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. In the response filed September 13, 2004, Applicant's election of Group IV, claims 72-73, without traverse, is acknowledged. Claims 33-73 are pending. Claims 33-71 are withdrawn from consideration, being drawn to non-elected inventions. Claims 72 and 73 are under examination.

#### ***Claim Objections***

2. Claims 72 and 73 are objected to because of the following informalities: Claims 72 and 73 depend from non-elected claims. While the subject matter of the claims can be ascertained, the claims should be amended to recite the limitations of the previous claims. Because Applicant elected Group IV, drawn to a method for altering antigenicity of adeno associated virus (AAV) using a structural protein, the subject matter relating to nucleic acids, cells comprising the nucleic acids, transformation of cells and gene therapy should be removed from the claims. The claims are examined only with regard to a method for altering antigenicity using a structural protein (as defined in claim 33). Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 72 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. While all of the technical details of a method need not be recited, the

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claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps minimally include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay allow for the determination. In the instant case, the claims are drawn to a method of altering the antigenicity of AAV comprising using a structural protein of AAV that has been modified in such a way to bring about reduction in the antigenicity of AAV virus. While the method provides a reagent for performing the method, there are no method steps about "using a ... structural protein". Is an AAV comprising the modified protein administered? As written, the claims only use a structural protein, which by itself is not an entire virus to be antigenically altered. Further, the structural protein must bring about a reduction in the antigenicity of the virus. The metes and bounds of "reduction" in antigenicity are not clearly defined in the specification, and the word itself lacks comparative basis and is therefore subject to individual interpretation. The specification discloses detecting reduced humoral immune responses and cellular responses (page 6, second and third full paragraphs). However, Applicant has defined the methods of determining a "reduction in antigenicity" using other relative terms, such as, "considerably less well", and "not being so strongly stimulated". Therefore, complete method steps and definite terms are required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 72 and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Mamounas *et al.* (WO 97/38723, herein, “Mamounas”). The claims are drawn to a method for altering the antigenicity of AAV comprising using a structural protein of AAV that has been modified in such a way to bring about reduction in the antigenicity of AAV virus. Also claimed for use in the method is a modified structural protein of AAV having an additional modification.

According to the specification, a modification can be a covalent or non-covalent linkage of a molecule to an amino acid or sequence (page 9, first full paragraph). A modification can also be a mutation in the amino acid sequence of the structural protein (page 9, second full paragraph).

A modification can also be an insertion into the protein (page 10, lines 4-10).

Mamounas discloses a capsid protein (structural protein) of AAV that has been deleted (modified) in the VP1 or VP3 region. The deletion results in reduced specificity of the virus for the AAV receptor (page 4, lines 22-26), which is an alteration of the antigenicity of the virus. Mamounas also teaches deleting a region of the VP1 or VP3 region and expressing a targeting ligand, which is an additional modification (page 4, lines 28-31). Therefore, the claims are anticipated by Mamounas.

### ***Conclusion***

5. No claim is allowed. Claims 72-73 are rejected.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen  
November 5, 2004